

Exhibit E

FILED
05 JUN -6 PM 2:00
CLERK U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY: *[Signature]*
DEPUTY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

ROBERT V. PURCELL, Plaintiff, v. MERCK & CO., INC., a New Jersey corporation; McKESSON CORP., a California corporation, Defendants.

Civil No. 05cv0443-L(BLM)

ORDER: (1) GRANTING DEFENDANT MERCK & CO., INC.'S *EX PARTE* APPLICATION TO STAY; (2) DENYING PLAINTIFF'S MOTION TO STRIKE; AND (2) DENYING WITHOUT PREJUDICE PLAINTIFF'S MOTION TO REMAND

[Docket Nos. 7, 16, 17]

This matter comes before the Court on: (1) Defendant Merck & Co., Inc.'s *Ex Parte* Application for an Order Staying All Proceedings Pending the Transfer Decision by the Judicial Panel on Multidistrict Litigation; and (2) Plaintiff's Motion to Remand. The Court finds these matters suitable for determination on the papers and without oral argument in accordance with Civil Local Rule 7.1(d)(1).

BACKGROUND

Defendant Merck manufactured, marketed, and sold the pain prescription drug VIOXX beginning in 1999. On September 30, 2004, Merck voluntarily withdrew VIOXX from the market, citing "an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking VIOXX® compared with those taking placebo." (McDonald-Hicks Decl. ¶ 2.) As of that date, numerous cases regarding VIOXX had been filed

1 throughout the nation. *Id.* ¶ 3. Following Merck's voluntary withdrawal of the drug off the
2 market, hundreds of additional lawsuits regarding VIOXX were filed.

3 Plaintiff filed an action in San Diego Superior Court against Merck on October 13, 2004.
4 (Merck's Notice of Removal ¶ 1.) On October 19, 2004, Merck removed the case to this Court,
5 and six days later Plaintiff voluntarily dismissed the action. *Id.* Plaintiff re-filed the action in
6 San Diego Superior Court, and on January 27, 2005 filed an amended complaint against Merck
7 and McKesson Corporation, alleging: violation of California Consumer Legal Remedies Act;
8 unfair competition; unjust enrichment; conversion; negligence; and strict products liability.

9 On February 16, 2005, the Judicial Panel on Multidistrict Litigation ("JPML") established
10 Multidistrict Litigation ("MDL") Proceeding No. 1657, *In re VIOXX Products Liability*
11 *Litigation*, and directed 148 actions from 41 federal districts to be transferred to Judge Eldon E.
12 Fallon of the Eastern District of Louisiana for coordinated pretrial proceedings. (McDonald-
13 Hicks Decl. ¶ 4; McDonald-Hicks Decl. Ex. A.) All of these actions focus on alleged increased
14 health risks when taking VIOXX, and whether Merck knew of these increased risks and failed to
15 disclose them to the medical community and consumers. (McDonald-Hicks Decl. Ex. A at 2.)

16 On March 4, 2005, Merck removed this action to this Court based on diversity
17 jurisdiction. Merck asserted that although McKesson is a California corporation, it was
18 fraudulently joined in this lawsuit and therefore its citizenship should not be considered for
19 jurisdictional purposes. Shortly thereafter, Merck filed an *Ex Parte* Application for an Order
20 Staying All Proceedings Pending the Transfer Decision by the Judicial Panel on Multidistrict
21 Litigation.

22 The JPML's April 5, 2005 Conditional Transfer Order No. 5 transferred this case to the
23 MDL proceeding. (McDonald-Hicks Decl. ¶ 5; *id.* Ex. B.) Plaintiff filed an objection to transfer
24 with the MDL court, and its motion to vacate the Conditional Transfer Order will be heard at the
25 next JPML hearing session. *Id.* ¶ 5.

26 On April 13, 2005, Plaintiff filed a motion to remand, arguing that McKesson is a
27 properly-named party to this action, and because it is a California corporation, this Court cannot
28 exercise diversity jurisdiction over this action.

LEGAL STANDARDS

I. Motions to Remand

The federal court is one of limited jurisdiction. *See Gould v. Mut. Life Ins. Co. of N.Y.*, 790 F.2d 769, 774 (9th Cir. 1986). As such, it cannot reach the merits of any dispute until it confirms its own subject matter jurisdiction. *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 94 (1998). “Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.” *Id.* (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 614 (1868)). District courts must construe the removal statutes strictly against removal and resolve any uncertainty as to removability in favor of remanding the case to state court. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992) (per curiam); *Boggs v. Lewis*, 863 F.2d 662, 663 (9th Cir. 1988).

12 Removal jurisdiction is governed by 28 U.S.C. § 1441. A state court action can only be
13 removed if it could have originally been brought in federal court. *Caterpillar, Inc. v. Williams*,
14 482 U.S. 386, 392 (1987); *Duncan v. Stuetzle*, 76 F.3d 1480, 1485 (9th Cir. 1996). Thus, where
15 removal is based upon diversity jurisdiction, the defendant must show (1) complete diversity
16 among opposing parties and (2) an amount in controversy exceeding \$75,000. See 28 U.S.C. §
17 1332(a).

18 || II. Motions to Stay

19 A district court's discretion to stay an action pending a ruling on the transfer of a case to
20 an MDL court "is incidental to the power inherent in every court to control the disposition of the
21 causes on its docket with economy of time and effort for itself, for counsel, and for litigants."
22 *Landis v. American Water Works & Elec. Co.*, 299 U.S. 248, 254 (1936). When ruling on a
23 motion to stay, the district court should consider three factors: "(1) potential prejudice to the
24 non-moving party; (2) hardship and inequity to the moving party if the action is not stayed; and
25 (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases are in
26 fact consolidated." *Rivers v. Walt Disney Co.*, 980 F. Supp. 1358, 1360 (C.D. Cal. 1997).

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DISCUSSION

2 Merck seeks a stay of this action pending the JPML's decision whether to transfer this
3 action to the MDL court. Plaintiff objects to a stay, arguing the remand motion must be decided
4 first, and contends diversity jurisdiction does not exist. Merck responds that numerous courts
5 have determined judicial efficiency and consistency are promoted by deferring ruling on pending
6 remand motions until after the JPML has transferred a case.¹

7 Although generally this Court would address matters relating to subject matter
8 jurisdiction first, the possibility this case may be transferred to Judge Fallon and become part of
9 the MDL action persuades this Court to stay this action. The pendency of a remand motion does
10 not bar inclusion in an MDL proceeding, as the transferee court can decide the motion. *In re Ivy*,
11 901 F.2d 7, 9 (2d Cir. 1990). Indeed, the JPML noted this general rule when first creating the
12 VIOXX MDL proceeding. (McDonald-Hicks Decl. Ex. A at 2.)

13 The Court concurs with the decisions of other district judges finding that judicial
14 economy and efficiency are best served by a stay. This action, like the ones in the MDL
15 proceeding, alleges that Merck misrepresented VIOXX's safety and failed to disclose material
16 information regarding the drug's side effects. (Amended Compl. ¶ 13.) Accordingly, it appears
17 this case contains "one or more common questions of fact" with the MDL action that may
18 warrant its transfer to the Eastern District of Louisiana. *See* 28 U.S.C. § 1407. Further, it is
19 apparent that whether certain defendants have been fraudulently joined is an issue common to
20 several of the cases being considered for consolidation by the JPML. (*See* McDonald-Hicks

21 | //

¹ In support of its motion to stay, Merck cited to and attached numerous unpublished orders from district courts throughout the country. Plaintiff objects to Merck's reliance on those decisions, and has filed a motion to strike their citation under Ninth Circuit Rule 36-3. Plaintiff's argument is without merit. This Court, as well as others in this Circuit, have held that Ninth Circuit Rule 36-3 only applies to unpublished decisions from the Ninth Circuit and does not bar citation to unpublished opinions of courts other than the Ninth Circuit. *Herring v. Teradyne, Inc.*, 256 F. Supp. 2d 1118, 1128 n.2 (S.D. Cal. 2002); *Alvarenga-Villalobos v. Reno*, 133 F. Supp. 2d 1164, 1168 (N.D. Cal. 2000); *In re Antablian*, 140 B.R. 534, 536 (C.D. Cal. 1992). Although these unpublished decisions are not binding, the Court can consider them when ruling on Merck's application. See *Herring*, 256 F. Supp. 2d at 1128 n.2. Accordingly, Plaintiff's Motion to Strike Citation, Reference, and Lodgment of Non-Published Authorities is DENIED.

1 Decl. ¶ 12.) By allowing a single court to determine this issue, judicial resources will be
2 conserved and the risk of inconsistent rulings is avoided.

Under the circumstances presented, the potential prejudice to Plaintiff is minimal as the JPMPL should be soon considering his motion to vacate the Conditional Transfer Order. If the JMPL grants Plaintiff's motion, Plaintiff may renew his motion to remand with this Court. In contrast, the risk of hardship to Merck is great absent a stay. Given the numerous actions currently pending, Merck faces a significant risk of duplicate discovery and motion practice should this case proceed. This Court agrees with Judge Paul Huck of the United States District Court for the Southern District of Florida and Judge M. Christina Armijo of the United States District Court for the District of New Mexico that the hundreds of pending VIOXX cases "should, as a general proposition, be treated consistently so that no one plaintiff or plaintiff group has an advantage over the others with regard to the ability to prosecute claims in a timely manner." *Fontanilles v. Merck & Co.*, Case No. 04-22799-CIV-HUCK (S.D. Fla. Dec. 14, 2004); *Pace v. Merck & Co.*, No. CIV 04-1356 MCA/ACT (D. N.M. Jan. 10, 2005). Accordingly, the Court will grant Merck's motion to stay and deny without prejudice Plaintiff's motion to remand.

CONCLUSION

Having reviewed the parties' briefs and applicable law, and considered the interests of
judicial economy and consistency, **IT IS HEREBY ORDERED:**

20 1. Merck's *Ex Parte* Application for an Order Staying All Proceedings Pending the
21 Transfer Decision by the Judicial Panel on Multidistrict Litigation is **GRANTED**.
22 2. This action is **STAYED** pending a final transfer decision by the JPML.
23 3. Plaintiff's Motion to Strike Citation, Reference, and Lodgment of Non-Published
24 Authorities is **DENIED**.
25 4. Plaintiff's Motion to Remand is **DENIED WITHOUT PREJUDICE**. Plaintiff may
26 renew his motion to remand if this case is not transferred to the MDL action.

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1 5. Should the JPML decide this action will not be transferred to the MDL proceeding,
2 Plaintiff shall notify the Court in writing within 10 days of the JPML's decision and should
3 contact chambers to schedule a hearing date on a renewed motion to remand.

4 **IT IS SO ORDERED.**

5 Dated: 6/3/05


M. JAMES LORENZ
UNITED STATES DISTRICT JUDGE

6 COPY TO:

7 HON. BARBARA L. MAJOR
8 UNITED STATES MAGISTRATE JUDGE

9 ALL PARTIES/COUNSEL

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Exhibit F

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U.S. DISTRICT COURT
EAST DISTRICT OF TEXAS
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LORETTA A.G. WHYTE
CLERK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

**CHARLES C. FOTI, JR., ATTORNEY GENERAL
for the State of Louisiana, as *parens patriae* on behalf
of the STATE OF LOUISIANA, and
THE CITIZENS OF THE STATE OF LOUISIANA,
and the LOUISIANA DEPARTMENT OF HEALTH
& HOSPITALS**

Plaintiffs,

§ CIVIL ACTION NO. 65-3700

JUDGE

MAGISTRATE JUDGE

VERSUS

MERCK & CO., INC.

Defendant.

38

NOTICE OF REMOVAL OF MERCK & CO., INC.

PLEASE TAKE NOTICE that defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Civil District Court within and for the Parish of Orleans to the United States District Court for the Eastern District of Louisiana, pursuant to 28 U.S.C. §§ 1331, 1332, and 1441, because the action is subject to both federal question and diversity jurisdiction. Defendant respectfully states to this Court the following:

1. This action involves allegations regarding the prescription drug VIOXX®.

On February 16, 2005, the Judicial Panel on Multidistrict Litigation issued an order transferring 139 VIOXX® products liability cases to the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407. Upon removal to the Eastern District, Merck intends to designate this action as related to the

consolidated MDL Action before Judge Fallon and seek to have it consolidated in MDL No. 1657.

2. On July 6, 2005, the Attorney General of Louisiana, on behalf of the State of Louisiana and its citizens, as well as the Louisiana Department of Health and Hospitals ("Plaintiff"), commenced this action in the Civil District Court for the Parish of Orleans against Merck, captioned *Charles C. Foti, Jr., Attorney General for the State of Louisiana, as parens patriae on behalf of the State of Louisiana, the Citizens of the State of Louisiana, and the Louisiana Department of Health and Hospitals v. Merck Co., Inc.*, No. 2005-9085.

3. Merck has not yet been served with a copy of the Petition for Injunctive Relief and Damages ("Petition"). Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b). Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings and orders served on or by Merck in the state court action are attached hereto as composite Exhibit A.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 98(a), because it is the "district and division embracing the place where such action is pending." See 28 U.S.C. § 1441(a). No previous application has been made for the relief requested herein.

I. ALLEGATIONS AND REQUESTED RELIEF

5. The Petition alleges against Merck causes of action based upon the Louisiana law of redhibition, LA. CIV. CODE art. 2520, *et seq.*, the Louisiana Products Liability Act, LA. REV. STAT. 9:2800.51 *et seq.* ("LPLA"), and the Louisiana Unfair Trade Practices Act, LA. REV. STAT. § 51:1401, *et seq.* ("LUTPA"), as well as state common law theories of negligence and unjust enrichment. Merck is alleged in the main to have violated these laws by aggressively marketing and selling the prescription drug VIOXX® by misleading the Food and Drug Administration ("FDA") and potential users about the drug and by failing to warn

adequately of adverse health effects that Merck knew or should have known resulted from use of the drug. Petition ("Pet.") ¶ 16. The Petition alleges that Merck's suppression of evidence, including its own medical and clinical research, regarding an increased risk of cardiovascular and/or cerebrovascular problems, from the FDA and the public, and Merck's misleading marketing resulted in widespread use of VIOXX®, including by residents of Louisiana, and serious injuries to users, at a time when other safer, cheaper, and effective drugs were available to them. *Id.* The Petition further alleges that Merck requested that VIOXX® be placed on Louisiana's Medicaid formulary and that in doing so, Merck directly or implicitly represented to Plaintiff that VIOXX® was safe, and thereby caused the Louisiana Department of Health and Hospitals ("DHH") to expend substantial sums for VIOXX® prescriptions for Medicaid recipients and for the treatment of their allegedly VIOXX®-related injuries. *Id.* ¶¶ 17, 18, 21, 22, 53, 57. As a result of these actions, the Petition alleges, Merck reaped billions of dollars in profits at the expense of the health of Louisiana citizens. *Id.* ¶ 19.

6. The Petition alleges that Merck is liable to Plaintiff in rehhibition for a return of the purchase price of VIOXX® paid by the state Medicaid program, including interest, all expenses occasioned by the sale of VIOXX®, costs, penalties, and attorneys' fees. *Id.* ¶ 33. The Petition specifies that the DHH is entitled to actual damages, reasonable attorneys' fees, and costs, engendered by its having paid millions of dollars to purchase VIOXX® for Louisiana Medicaid recipients and to pay for treatment for their VIOXX®-related injuries. *Id.* ¶ 53. The Petition also seeks pursuant to the LUTPA a permanent injunction against Merck from returning VIOXX® to the Louisiana market, as well as financial restitution and other monetary damages sustained. *Id.* See also Prayer for Relief ¶¶ 1-8.

7. This Court has original jurisdiction over this matter on two independent grounds. First, pursuant to 28 U.S.C. §1331, federal question jurisdiction exists, because the Plaintiff's claims are premised upon Merck's having violated regulations promulgated and enforced by the FDA; therefore, the claims arise under the laws of the United States. Second, pursuant to 28 U.S.C. §1332(a), diversity jurisdiction exists in that the amount in controversy, exclusive of interest and costs, exceeds the sum of \$75,000, and there is complete diversity of citizenship between Plaintiff Louisiana Department of Health and Hospitals ("DHII"), the only real plaintiff-party in interest, and Defendant Merck. Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

II. FEDERAL QUESTION JURISDICTION

8. The claims in this case are implicitly premised upon alleged violations of the Federal Food, Drug & Cosmetic Act ("FDCA") – namely that Merck illegally promoted an unsafe drug for public use and failed to warn adequately the FDA, the DHII, and Louisiana residents of risks, in violation of FDCA rules and regulations. Under the FDCA, the FDA (not the Louisiana Attorney General) is tasked with approving drugs for human use and determining the necessary warnings manufacturers must include with their products. 21 U.S.C. §393(b)(1).

9. The FDCA charges the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et. seq.* 21 U.S.C. § 371(a).

10. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research ("CDER"). The CDER oversees the drug companies' development,

testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug's benefits against its risks and to make an approval decision. The CDER also ensures truth in advertising for prescription drugs, in part by approving Package Inserts that properly outline benefit and risk information. Once drugs are marketed, they are still monitored by the CDER for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. In short, CDER evaluates and monitors the effectiveness and safety of prescription drugs. The Petition itself makes clear the FDA's central role and oversight in assessing safety studies related to VIOXX®, implementing labeling changes to apprise the public of risks associated with use of the drug, and continuing to review new safety studies to determine the necessity of further labeling changes. Pet. ¶¶ 10-14.

11. The Petition creates substantial federal question jurisdiction, because even though the claims are styled as being premised on state law, (1) a federal right is an essential element of Plaintiff's claims; (2) interpretation of the federal right is necessary to resolve the case; and (3) the question of federal law is substantial. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 917 (5th Cir. 2001). In *Howery*, the court suggested that fulfillment of the first prong of this test turns on whether a violation of a federal statute is an element of the state statute at issue. A key statute on which Plaintiff's claims are based is the LUTPA, which incorporates violations of federal law as a basis for liability. The LUTPA is almost identical to the Federal Trade Commission Act ("FTC Act"), and therefore Louisiana courts have used the standard used by the Federal Trade Commission to determine what constitutes an unfair act or practice. See, e.g., *State ex rel. Guste v. Orkin Exterminating Co.*, 528 So. 2d 198, 201 (La. App. 4 Cir. 1988) (citations to FTC opinions omitted).

12. Moreover, it is primarily the lawful disbursement of *federal funds* (not state funds) that is at issue in this case, because federal funds comprise the majority of the Louisiana Medicaid Program's funds, which are dispensed by the DHH and which comprise the bulk of the damages this action seeks to recover. For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 71.63% of Louisiana Medicaid financing. See *Federal Register*: November 15, 2002 (Volume 67, Number 221), *Federal Medical Assistance Percentages and Enhanced Federal Medical Assistance Percentages for Fiscal Year 2004*, available at <http://www.aspe.hhs.gov/health/fmap04.htm>. Thus, the majority of the money Plaintiff seeks to recoup through this lawsuit is federal money.

13. The second and third elements of the *Howery* test are satisfied because the meaning of the FDCA and its attendant regulations are central to the question of whether Merck violated Louisiana law in marketing and making communications regarding the safety of VIOXX®. Federal law-based illegality is the basis for Plaintiff's claim for reimbursements for VIOXX-related expenditures. In short, Plaintiff ties its recovery to whether Merck's alleged statements and disclosures to the FDA and the DHH about the safety and efficacy of VIOXX® — communications that are based upon the prescribing information, which is vetted and approved by the FDA in compliance with federal law — were in fact misrepresentations.

14. Communications and promotional materials directed to doctors, consumers, and state regulators about prescription medication consistent with the prescribing information are monitored by the FDA to ensure the provision of accurate risk/benefit information. A finding that Merck made misrepresentations to the FDA and the DHH concerning VIOXX® requires findings that the VIOXX® labeling and statements violated the FDCA.

15. Less than two months ago, in *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, the U.S. Supreme Court recognized that “a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify the resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, No. 04-605, Slip Op. at 3 (2005). As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action (as some federal courts have held), but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state responsibilities.” *Id.* at 5. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because (as in this case) the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its responsibilities as defined by federal law. Thus, federal question jurisdiction existed because the meaning of the federal law was an essential element of the state law claim. *Id.* at 6.

16. Courts have applied *Grable* in Louisiana actions, like this one, in which plaintiffs’ state law claims are premised on violations of the FDCA and its rules and regulations. For example, a court found jurisdiction in a suit brought by the State of Louisiana against the manufacturers of the drug Zyprexa for reimbursement of Medicaid payments because of the “substantial federal funding provisions involved” and because allegations that the manufacturer had failed to follow federally proscribed safety procedures rendered the case “federally oriented.” *In re Zyprexa Products Liability Litigation*, No. 04-MD-01596, Slip Op. at 4

(E.D.N.Y. Jul. 1, 2005) (attached hereto as Exhibit "B"). This rationale applies equally to this case.

17. For all of these reasons, Plaintiff's claims present a substantial federal question, and this Court is therefore vested with original jurisdiction.

III. DIVERSITY JURISDICTION

18. Pursuant to 28 U.S.C. § 1332(a), diversity jurisdiction also exists over this case because the amount in controversy, exclusive of interest and costs, exceeds the sum of \$75,000.00, and there is complete diversity of citizenship between the DHH, a Louisiana citizen that is the only real plaintiff-party in interest, and Defendant, a corporate citizen of New Jersey. Therefore, this action may be removed to this Court, pursuant to 28 U.S.C. § 1441.

19. First, the DHH is the real party in interest on the plaintiff's side of this case, because it is the entity that holds the substantive right sought to be enforced, even if it is not the entity that will ultimately benefit from any recovery. *See Farrell Constr. Co. v. Jefferson Parish, Louisiana*, 896 F.2d 136 (5th Cir. 1990). This is an action that primarily alleges fraud upon the Louisiana Medicaid Program and seeks to recover primarily Medicaid funds. The DHH is the agency that independently operates and administers the Louisiana Medicaid Program. Its "primary responsibility" is to ensure "the delivery of state health and human services in a manner that maximizes the use of federal, state, and local funds," and its first goal is to "maximize federal funds through the efficient use of available state and local resources." §§ 531.002(b)(2), 531.001(1). Thus, in essence, Plaintiff's claims under Louisiana law is that Defendant, through the alleged misrepresentations regarding VIOXX®, defrauded the DHH, making the DHH the real party in interest and the Attorney General merely its advocate and a formal party to this litigation whose non-citizen status does not defeat diversity.

20. Second, the DHH is independent of the State of Louisiana, and thus is a Louisiana citizen for purposes of jurisdiction under 28 U.S.C. § 1332. *Moor v. County of Alameda*, 411 U.S. 693 (1973). "In determining whether the agency is an alter ego of the state or an independent agency, the essential question is whether the state is the real party in interest in the lawsuit." *Tradigrain, Inc. v. Mississippi State Port Authority*, 701 F.2d 1131, 1132 (5th Cir. 1983). As set forth above, the DHH is the real party in interest in this suit. Its "real party in interest" status is confirmed by its fulfillment of the factors cited in *Tradigrain* to facilitate the assessment of an agency's independence. In short, the DHH is an independent entity whose citizenship counts for diversity purposes, because it exercises a high degree of financial and operational autonomy from the State of Louisiana. *See Texas Dep't of Housing & Community Affairs v. Verex Assurance, Inc.*, 68 F.3d 922, 926 (5th Cir. 1995). Louisiana law charges the DHH and its Secretary with the sole responsibility for financially operating and administering the Louisiana Medicaid Program, including the allocation of all federal funds provided to the program. LA. REV. STAT. ANN. § 36:254 (West 2004).

21. In addition to its autonomy in the funding and administration of its medical assistance programs, the DHH functions independently of the state, such that it is a Louisiana citizen for purposes of diversity. For example, the Secretary of the DHH sets the entity's policies, makes and promulgates rules necessary to its function, and advises the governor on its administration. LA. REV. STAT. ANN. § 36:254(A) (West 2004). In addition, the Secretary allocates funding among medical education institutions, employs personnel, and grants rights of way and servitudes on state-owned lands under his jurisdiction. *Id.*

22. In fact, the United States Court of Appeals for the Fifth Circuit has held that a state agency similar to the DHH, the Florida Department of Health and Rehabilitative

Services ("FDHRS"), was an independent state agency over which the federal court could exercise jurisdiction. *See Dept. of Health & Rehab. Svcs., State of Florida v. Davis*, 616 F.2d 828, 833 (5th Cir. 1980). In affirming the exercise of jurisdiction in that case, the court stated that diversity jurisdiction extends to "a suit between a state agency and a citizen of another state, where the agency is invested with the power to sue and be sued, and possesses other generally recognized corporate powers." *Id.* at 833. The powers of the DHH are analogous to those of the FDHRS. Thus, the DHH is likewise independent of the state and a Louisiana citizen for diversity purposes, especially with respect to an action that seeks to recoup funds the DHH was allegedly wrongfully caused to expend.

23. Merck is, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, White House Station, New Jersey and, therefore, is a citizen of New Jersey for purposes of determining diversity. 28 U.S.C. § 1332(c)(1).

24. The amount in controversy far exceeds \$75,000, exclusive of interests and costs, as required under 28 U.S.C. § 1332. The Petition seeks, in part, a return of the purchase price of VIOXX® paid by the state Medicaid program, including interest; all expenses occasioned by the sale of VIOXX®; and all damages sustained by the DHH, which amount to "millions of dollars." Pet. ¶ 33.

IV. FULFILLMENT OF PROCEDURAL REQUIREMENTS

25. Service was not been effected on Defendant. Accordingly, this Notice of Removal is timely under 28 U.S.C. § 1446(b).

26. Defendant will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the Civil District Court of the Parish of Orleans, State of

Louisiana, in accordance with 28 U.S.C. § 1446(d); and (b) serve Plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

27. In filing this Notice of Removal, Defendant does not waive either any defenses or arguments available to it in this action, or its right to challenge any causes of action, arguments, or allegations proposed by Plaintiffs.

WHEREFORE, Defendant Merck prays that the above numbered and entitled cause of action on the docket of the Civil District Court of the Parish of Orleans, State of Louisiana, be removed from that court to the docket of the United States District Court for the Eastern District of Louisiana, in accordance with 28 U.S.C. § 1441.

Dated: August 5, 2005

Respectfully submitted,

Thomas Owen Jr.

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Attorneys for Merck & Co., Inc.

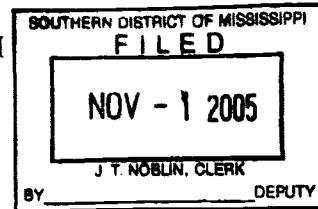
CERTIFICATE OF SERVICE

I hereby certify that the above and foregoing Notice of Removal of Defendant Merck & Co., Inc. has been served on all counsel of record by fax and/or U. S. Mail, and on Liaison Counsel, Russ Herman and Phillip Wittmann, by U.S. Mail and e-mail or by hand delivery and e-mail, on this 5th day of August, 2005.

Thomas Owen Jr.

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION



JIM HOOD, ATTORNEY GENERAL *ex rel.*,
STATE OF MISSISSIPPI,
Plaintiff,
v.
MERCK & CO., INC.,
Defendant.

) Case No.: 3:05cv6661TW-JOS

NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC.

PLEASE TAKE NOTICE that defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Chancery Court within and for the First Judicial District of Hinds County, Mississippi to the United States District Court for the Southern District of Mississippi, pursuant to 28 U.S.C. §§ 1331, 1332, and 1441, because the action is subject to both federal question and diversity jurisdiction. Merck respectfully states to this Court the following:

1. This action involves allegations regarding the prescription drug Vioxx® ("Vioxx"). On February 16, 2005, the Judicial Panel on Multidistrict Litigation issued an order transferring 139 Vioxx products liability cases to the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407. Merck intends to seek the transfer of this action to that multidistrict litigation, *In re VIOXX Products Liability Litigation*, MDL No. 1657, and will shortly provide the MDL Panel notice of this action pursuant to the "tag-along" procedure contained in the MDL Rules.

2. On October 4, 2005, the State of Mississippi (“the State”) commenced this action in the Chancery Court of Hinds County, Mississippi, against Merck, captioned *Jim Hood, Attorney General ex rel., State of Mississippi v. Merck & Co., Inc.*, Civ. Action No. G2005-1742 w/4.

3. On October 5, 2005, Merck was served with a copy of the Complaint. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b). Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings and orders served on or by Merck in the state court action are attached hereto as composite Exhibit A.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 89(c), because it is the “district and division embracing the place where such action is pending.” See 28 U.S.C. § 1441(a). No previous application has been made for the relief requested herein.

I. ALLEGATIONS AND REQUESTED RELIEF

5. The State of Mississippi alleges that Merck violated the Mississippi Consumer Protection Act, § 75-24-1, *et seq.* (“MCPA”), the Mississippi Deceptive Advertising statute, § 97-23-3 (“MDA”), the Medicaid Fraud Control Act, § 43-13-201 *et seq.* (“MFCA”), and the Mississippi Products Liability Act, § 11-1-63 (“MPLA”), and also alleges claims based on theories of common law fraud, unjust enrichment, negligence, and indemnity. The basis for these claims is Merck’s alleged numerous public false and misleading statements and omissions of material facts from 1999-2003 concerning the safety and efficacy of Vioxx, which Merck made primarily through press releases and primarily to conceal the drug’s cardiovascular risks from the Food and Drug Administration (“FDA”) and the state citizenry. (Complaint (“Compl.”) ¶¶ 18-80.) As a result of these statements, the State and its citizens allegedly were damaged (1) by paying excessive amounts for Vioxx instead of smaller amounts on equally effective and

cheaper drugs in the same class, and (2) by ingesting Vioxx and being exposed to its adverse health effects. (*Id.* ¶89.) In terms of damages, the State seeks recovery of civil penalties pursuant to the MCPA; the full amount Merck allegedly received as a result of payments made by the Mississippi Department of Medicaid for Vioxx and an additional civil penalty equal to triple that full amount, pursuant to the MFCA; and compensatory damages, punitive damages, and attorneys' fees. (*Id.* Prayer for Relief.)

6. This Court has federal question jurisdiction over this matter, pursuant to 28 U.S.C. § 1331, because the State's claims essentially are premised on Merck's having violated regulations promulgated and enforced by the FDA under statutory authority conferred by the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* In addition, the State's claims raise important federal questions related to the federal Medicaid statute and its underlying regulations.

II. FEDERAL QUESTION JURISDICTION

7. The claims in this case are implicitly premised upon alleged violations of the Federal Food, Drug & Cosmetic Act ("FDCA") – namely that Merck illegally promoted an unsafe drug for public use and failed to warn adequately state regulators and consumers of risks in violation of FDCA rules and regulations. Under the FDCA, the FDA (not the Mississippi Attorney General) is tasked with approving drugs for human use and determining the necessary warnings manufacturers must include with their products. 21 U.S.C. §393(b)(1).

8. The FDCA charges the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce

the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et. seq.* 21 U.S.C. § 371(a).

9. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research (“CDER”). The CDER oversees the drug companies’ development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug’s benefits against its risks and to make an approval decision. The CDER also ensures truth in advertising for prescription drugs, in part by approving Package Inserts that properly outline benefit and risk information. Once drugs are marketed, they are still monitored by the CDER for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. In short, CDER evaluates and monitors the effectiveness and safety of prescription drugs.

10. The State’s complaint creates substantial federal question jurisdiction, because even though the claims are styled as being premised on state law, (1) a federal right is an essential element of the State’s claims; (2) interpretation of the federal right is necessary to resolve the case; and (3) the question of federal law is substantial. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 917 (5th Cir. 2001). In *Howery*, the court suggested that fulfillment of the first prong of this test turns on whether a violation of a federal statute is an element of the state statute at issue. The Mississippi statutes pursuant to which the State purports to state its claims, including the Deceptive Advertising statute and the Mississippi Consumer Protection Act, implicitly incorporate violations of federal law as a basis for liability because any finding that Merck, as the Complaint alleges, had falsely represented the safety of Vioxx to the FDA, which approves drugs for use in every state of the nation including Mississippi, would be a finding that

Merck had violated those statutes. Moreover, it is primarily the lawful disbursement of *federal funds* (not state funds) that is at issue, because federal funds comprise the majority of Mississippi Medicaid funds. For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 77.08% of Mississippi Medicaid financing, the highest of any state in the nation. *See Federal Register: November 15, 2002 (Volume 67, Number 221), Federal Medical Assistance Percentages and Enhanced Federal Medical Assistance Percentages for Fiscal Year 2004, available at* [*http://www.aspe.hhs.gov/health/fmap04.htm*](http://www.aspe.hhs.gov/health/fmap04.htm)*. Thus, the vast majority of the money the State seeks to recoup through this lawsuit is federal money.*

11. The second and third elements of the *Howery* test are satisfied because the meaning of the FDCA and its attendant regulations are central to the question of whether Merck violated the Mississippi statutes at issue in marketing and making communications regarding the safety of Vioxx. Federal law-based illegality is the basis for the State's claim for reimbursements for Vioxx-related expenditures because the State ties its recovery to whether Merck's alleged public statements about the safety and efficacy of Vioxx — communications that are based upon the prescribing information that is vetted and approved by the FDA in compliance with federal law — were in fact fraudulent misrepresentations. The Complaint, indeed, makes this link clear, stating that Merck "failed to disclose to the FDA" material negative information known to the Merck concerning the cardiovascular risks of Vioxx and intimating that the FDA would not have approved the drug had it possessed this information. (Compl. ¶ 1; *see also id.* ¶ 24 bullet point #2.) The Complaint also points out how the FDA tracked Merck's public statements about the drug in noting that on December 16, 1999 and September 17, 2001, the FDA sent Merck letters allegedly admonishing Merck for aspects of its promotional activities and materials concerning Vioxx. (*Id.* ¶ 24 bullet point #4, ¶¶ 51-54.) The

Complaint further points out that Merck issued press releases and made statements to the press regarding administrative proceedings by the FDA with respect to the labeling of Vioxx in which Merck allegedly continued to conceal risk information from those proceedings and the public.

(Compl. ¶¶ 34-36, 75-76.)

12. Communications directed to state regulators and consumers about prescription medication consistent with the prescribing information are monitored by the FDA to ensure the provision of accurate risk/benefit information. A finding that Merck made misrepresentations to consumers and Mississippi officials concerning Vioxx requires findings that the alleged statements regarding Vioxx violated the FDCA.

13. Less than two months ago, in *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, the U.S. Supreme Court recognized that “a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify the resort to the experience, solicitude, and hope of uniformity that a federal form offers on federal issues.” *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, No. 04-605, Slip Op. at 3 (2005). As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action (as some federal courts have held), but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state responsibilities.” *Id.* at 5. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because (as in this case) the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its

responsibilities as defined by federal law. Thus, federal question jurisdiction existed because the meaning of the federal law was an essential element of the state law claim. *Id.* at 6.

14. Courts have applied *Grable* in actions, like this one, in which plaintiff's state law claims are premised on violations of the FDCA and its rules and regulations. For example, a court found jurisdiction in a suit brought by the State of Louisiana against the manufacturers of the drug Zyprexa for reimbursement of Medicaid payments because of the "substantial federal funding provisions involved" and because allegations that the manufacturer had failed to follow federally proscribed safety procedures rendered the case "federally oriented." *In re Zyprexa Products Liability Litigation*, No. 04-MD-01596, Slip Op. at 4 (E.D.N.Y. Jul. 1, 2005) (attached hereto as Exhibit B). The same rationale applies in this case.

15. For all of these reasons, the State's claims present a substantial federal question, and this Court is therefore vested with original jurisdiction.

III. FULFILLMENT OF PROCEDURAL REQUIREMENTS

16. Service was effected on Merck on October 5, 2005. Accordingly, this Notice of Removal is timely under 28 U.S.C. § 1446(b).

17. Merck will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the Chancery Court within and for the First Judicial District of Hinds County, State of Mississippi, in accordance with 28 U.S.C. § 1446(d); and (b) serve plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

18. In filing this Notice of Removal, Merck does not waive either any defenses or arguments available to it in this action, or its right to challenge any causes of action, arguments, or allegations proposed by plaintiff.

WHEREFORE, Defendant prays that the above numbered and entitled cause on the docket of the Chancery Court within and for the First Judicial District of Hinds County, State of Mississippi, be removed from that court to the docket of the United States District Court for the Southern District of Mississippi, in accordance with 28 U.S.C. § 1441.

DATED this 1st day of November, 2005.

Respectfully submitted,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

By:

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Exhibit H

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Attorneys for
MERCK & CO., INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

STATE OF ALASKA,

Case No. _____

Plaintiff,

vs.

MERCK & CO., INC.

Defendant

NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC.

PLEASE TAKE NOTICE that defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Superior Court for the State of Alaska, Third Judicial District at Anchorage to the United States District Court for the District of Alaska, pursuant to 28 U.S.C. §§ 1331 and 1441. In support of its removal, defendant respectfully states as follows:

1. This action involves allegations regarding the prescription drug Vioxx®.

An MDL proceeding has been established in the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings of Vioxx-related actions under 28 U.S.C. § 1407. Two other suits filed by the state attorneys

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general of Louisiana and Mississippi alleging similar claims against Merck are already pending in that MDL proceeding,¹ and Merck intends to seek the transfer of this action to that MDL proceeding as well.

2. On December 23, 2005, the State of Alaska ("the State") commenced this action in the Superior Court for the State of Alaska, Third Judicial District at Anchorage, against Merck, captioned State of Alaska v. Merck & Co., Inc., No. 3AN-05-14292 CI.

3. Merck was served with a copy of the Complaint ("Compl") on December 27, 2005. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b). Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings and orders served on or by Merck in the state court action are attached hereto as composite **Exhibit A.**

4. Venue is proper in this Court pursuant to 28 U.S.C. § 89(c), because it is the "district and division embracing the place where such action is pending." See 28 U.S.C. § 1441(a).

5. No previous application has been made for the relief requested herein.

6. Merck will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the Superior Court for the State of Alaska, Third Judicial District at Anchorage, in accordance with 28 U.S.C. § 1446(d); and (b) serve plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance

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¹ The two state attorney general actions are *Foti v. Merck* (Louisiana) (E.D. La. 05-3700), and *Hood v. Merck* (Mississippi) (E.D. La. 05-6755).

with 28 U.S.C. § 1446(d).

I. ALLEGATIONS AND REQUESTED RELIEF

7. Plaintiff's complaint alleges that Merck violated the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPCA"), AS 45.50.471, by misrepresenting the safety of Vioxx to the State, which paid for Vioxx on behalf of Medicaid participants. (See Compl. 12-18.) The State also alleges that Merck knowingly made claims under the Alaska Medicaid Program for a product that was substantially inadequate. (Compl. 19). The State seeks compensatory damages, restitution for the value of all payments that the State of Alaska made for Vioxx prescriptions under its Medicaid program, civil penalties of \$5,000 for each separate violation of the UTPCPA, treble damages, punitive damages, attorneys' fees and costs, and prejudgment and postjudgment interest. (Compl. Prayer for Relief.)

II. FEDERAL QUESTION JURISDICTION

8. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331, because the State's claims directly implicate two areas of federal law: the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., which regulates prescription drug manufacturers' public and promotional statements about prescription drugs; and federal Medicaid law, which determines both which drugs a state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. See 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

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9. The Supreme Court has recognized that federal question jurisdiction exists over claims that are asserted under state law if the state law claims implicate substantial federal questions. *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 125 S. Ct. 2363, 2369 (2005). See also *Hopkins v. Walker*, 244 U.S. 486, 490-491 (1917); *County of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 (WHA), 2005 U.S. Dist. LEXIS 34453 (N.D. Cal. Dec. 2, 2005) (attached hereto).

10. As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action , but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state responsibilities.” 125 S. Ct. at 2368. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its responsibilities as defined by federal law. Thus, federal question jurisdiction existed because the meaning of the federal law was an essential element of the state law claim. *Id.* The same is true here.

11. First, the claims in this case are implicitly premised upon alleged violations of the federal Food, Drug & Cosmetic Act (“FDCA”) – namely that Merck illegally promoted an unsafe drug for public use and failed to warn adequately doctors, state regulators, and consumers of risks in violation of FDCA rules and regulations.

12. Under the FDCA, the FDA is tasked with approving drugs for human use

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and determining the necessary warnings manufacturers must include with their products. 21 U.S.C. §393(b)(1). The FDCA charges the FDA to ensure that “drugs are safe and effective” for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by “promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products.” 21 U.S.C. § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 et. seq. 21 U.S.C. § 371(a).

13. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research (“CDER”). The CDER oversees the drug companies’ development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug’s benefits against its risks and to make an approval decision. The CDER also regulates prescription drug advertising, including the Package Inserts that outline benefit and risk information, and monitors marketed drugs for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. Under federal law, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4)(2005). Indeed, as plaintiff’s pleading points out, as part of its oversight of drug marketing, the FDA sent a letter to Merck specifically regarding the contents of its marketing materials for VIOXX.

(Compl. 10.)

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marketing and making communications regarding the safety of Vioxx will necessarily require the Court to interpret the meaning of the FDCA and its attendant regulations.

15. Second, plaintiff's claims implicate substantial questions of federal law under the federal Medicaid statute because they depend on the interpretation and application of federal statutory provisions that govern what can be included in or rejected from State Medicaid formularies, including Alaska's, and because federal funds comprise the majority of Alaska Medicaid Program's funds – the money at issue in this lawsuit.

16. The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 430.10, et seq. "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990). In Alaska, the Medicaid program is administered by the Department of Health and Social Services. See <http://www.hss.state.ak.us/dhcs>; 42 C.F.R. § 431.10(b)(1) (requiring states to designate "a single State agency . . . to administer or supervise the administration of the [Medicaid] plan").

17. Federal law expressly requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a rebate agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B). Thus, Alaska is required under federal law to reimburse

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companies for drugs, such as Vioxx, if the manufacturer complies with federal requirements.

18. The only time a state can exclude from its formulary a covered outpatient drug subject to a rebate agreement is “with respect to the treatment of a specific disease or condition for an identified population . . . if, based on the drug’s labeling . . . the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.” 42 U.S.C. § 1396r-8(d)(4)(C). But even in such a situation, a state cannot deny coverage altogether; rather, it must condition such reimbursement on prior authorization, meaning that the state may require that it approve the drug’s dispensation before it is dispensed. 42 U.S.C. § 1396r-8(d)(4)(D). And even a decision to require prior authorization must satisfy federally mandated requirements. 42 U.S.C. §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

19. In short, because the Alaska Medicaid program operates within this overarching federal regulatory framework, plaintiff’s claims alleging that Vioxx should not have been a part of that program necessarily implicate and turn on questions of federal Medicaid law.

20. Other courts have applied *Grable* and recognized that federal jurisdiction exists over actions, like this one, in which plaintiffs’ state law claims are premised on

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violations of the FDCA and its rules and regulations. For example, in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state-law claims involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid. The court found that references in the complaint to federal funding provisions and laws demonstrated "a core of substantial issues [that were] federally oriented." *Id.* at 172-73.

21. Similarly, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 (WHA), 2005 U.S. Dist. LEXIS 34453 (N.D. Cal. Dec. 2, 2005) (attached hereto), held that federal jurisdiction was proper under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. In concluding that the Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." The court noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Astra USA*, 2005 U.S. Dist. LEXIS 34453, at *16. In this case, plaintiff's claims involve two complex federal regulatory schemes: Medicaid and the FDCA.

22. Because plaintiff's claims here, like those in *Grable*, *Zyprexa*, and *Astra*

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USA, will necessarily involve substantial questions of law under federal drug and Medicaid statutes and regulations, this Court has federal question jurisdiction over plaintiff's claims.

WHEREFORE, Defendant prays that the above numbered and entitled cause on the docket of the Superior Court for the State of Alaska, Third Judicial District at Anchorage be removed from that court to the docket of the United States District Court for the District of Alaska, in accordance with 28 U.S.C. § 1441.

DATED this 17th day of January, 2006, at Anchorage, Alaska.

DORSEY & WHITNEY LLP

By: /s/ Jahna M. Lindemuth
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 17th day of January, 2006, a true and correct copy of this document was served on:

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by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ Jahna M. Lindemuth
Jahna M. Lindemuth, ABA #9711068
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APPENDIX OF UNPUBLISHED AUTHORITIES

CASE

County of Santa Clara v. Astra USA, Inc.,

No. C 05-03740 (WHA)

2005 U.S. Dist. LEXIS 34453 (N.D. Cal. Dec. 2, 2005)